

Remarks:

Claims 1 to 35 are now in the application. Claims 1 to 12 and 26 to 33 are subject to examination and claims 13 to 25 have been withdrawn from examination. Claims 1, 27, 29, 31, 32, and 33 have been amended. Claims 34 and 35 have been added.

REJECTION OF CLAIMS UNDER MILLS ET AL.

In items 1 to 7 on pages 2 to 4 of the above-identified final Office action, claims 1, 2, 5, 6, 9 to 11, 27, and 29 to 33 have been rejected as being fully anticipated by U.S. Patent No. 5,037,021 to Mills et al. (hereinafter "Mills") under 35 U.S.C. § 102(b).

Claims 1, 27, 29, 31, 32, and 33 have been amended to even more clearly distinguish over the prior art.

Anticipation under 35 U.S.C. § 102(b) requires the presence in a single prior art reference each and every element of a claimed invention arranged as in the claimed invention. See e.g., Eolas Technologies, Inc. v. Microsoft Corp., 399 F.3d 1325, 1335 (Fed. Cir. 2005). Where the elements of a claimed invention are configured differently or function differently, there is no anticipation. Lindemann Maschinenfabrik GMBH v. American Hoist and Derrick, Co., 730 F.2d 1452, 1459 (Fed. Cir. 1984) (lower

court erred finding anticipation when it treated "the claims as mere catalogs of separate parts, in disregard of the part-to-part relationship, set forth in the claims and that give the claims their meaning"). To determine whether prior art anticipates an invention, one must identify the elements of the claimed invention, determine their meaning in light of the specifications and prosecution history and identify corresponding elements disclosed in the allegedly anticipatory reference. Id.; SSIH Equipment S.A. v. U.S.I.T.C. 718 F.2d 365, 377 (Fed. Cir. 1983) (in determining whether prior art anticipates an invention, court must determine what the elements of a claim are and what the reference discloses). To anticipate a claimed invention, the elements disclosed in a prior art reference must function in substantially the same way to produce substantially the same result as in the claimed invention. Tate Eng'g v. U.S., 477 F.2d 1336, 1342 (Ct. Cl. 1973).

Before discussing the prior art in detail, it is believed that a brief review of the invention as claimed, would be helpful. Claim 1 calls for, *inter alia*, a medical method, including:

advancing a clip over body tissue, the clip having two substantially parallel arms each having a respective piercing portion and a bridge coupling the two arms, such

that the body tissue is located between the two arms and such that the clip applies force to the body tissue; and

subsequently bending the piercing portion of at least one of the two arms through more than one half a thickness of the body tissue, the two arms remaining substantially parallel throughout the time the piercing portion of the at least one arm is bent.

Claim 27 calls for, *inter alia*, a medical method, including the steps of:

providing a clip having:

two substantially parallel arms each having a piercing portion; and

a bridge coupling the two arms; and

bending the piercing portion of at least one of the two arms through more than one half a thickness of the folded portion at an angle to the longitudinal direction, the two arms remaining substantially parallel throughout the time the piercing portion of the at least one arm is bent..

Claim 29 calls for, *inter alia*, a medical method, including the steps of:

providing a clip having two substantially parallel arms
each having a respective piercing portion and a bridge coupling the two arms; and

subsequently bending the piercing portion of at least one of the two arms through the first portion of the fold and at least partially through the second portion of the fold,
the two arms remaining substantially parallel throughout
the time the piercing portion of the at least one arm is
bent.

Claim 31 calls for, *inter alia*, a medical method, including the steps of:

providing a clip having two substantially parallel arms and a bridge coupling the two arms, the two arms each having a
respective piercing portion; and

subsequently bending the piercing portion of at least one of the two arms to pierce through the first portion of the

folded body tissue and at least partially through the second portion of the fold at an angle to the longitudinal direction, the two arms remaining substantially parallel throughout the time the piercing portion of the at least one arm is bent.

Claim 31 calls for, *inter alia*, a medical method, including the steps of:

Claims 32 similarly provides for a clip having two substantially parallel piercing arms and the step of:

subsequently bending the piercing portion of at least one of the two arms at an angle to the longitudinal direction to pierce through the first portion of the folded body tissue and at least partially through the second portion of the fold, the two arms remaining substantially parallel throughout the time the piercing portion of the at least one arm is bent.

Claim 33 similarly provides for a clip having two substantially parallel piercing arms and the step of:

b) subsequently bending the piercing portion of at least one of the two arms through more than one of the thicknesses of the body tissue, the two arms remaining substantially parallel throughout the time the piercing portion of the at least one arm is bent.

As set forth above, each of the two substantially parallel arms of the clip has a respective piercing portion. Thus, claims 1, 27, 29, 31, 32, and 33 provide for a clip with two piercing portions. Nowhere does Mills disclose or suggest a clip with two piercing portions. While the Examiner has argued otherwise, Applicants respectfully suggest, as set forth in detail below, that he is mistaken. In fact, the Examiner clearly provides on page 3 that only "one of them is bent through the whole thickness of the both portions of tissue [see progression from Figure 5a to 5c]." Because Mills does not disclose a clip with two piercing portions, Mills cannot anticipate claims 1, 27, 29, 31, 32, or 33 of the instant application.

The Mills device shown in FIGS. 5a to 5c only works if the "first upwardly extending section" is NOT a piercing portion - in other words, it functions as it is intended to function only if the "first upwardly extending section" does not pierce the tissue fold. See Mills at col. 6, line 16. It is further noted

that suction through suction channel 204 cannot apply sufficient force to pierce the tissue with either the first upwardly extending section or the fourth section of the staple 209 because Mills requires the piston 205 to drive the fourth section "of the staple through the double layer of tissue so that its tip comes into contact with the anvil 260 and simultaneously deform[s] the remaining sections of the staple." Mills at col. 6, lines 20 to 28.

The Examiner has reiterated his Section 102(b) rejection over Mills based on the mistaken belief that Mills discloses a staple with two functionally piercing arms. Mills, however, discloses a staple wherein only one of its arms, the fourth section that is parallel to the bridge (see Mills at col. 6, lines 14 to 19 and lines 25 to 28), is a piercing arm that pierces gathered tissue. Nowhere does Mills indicate that the first upwardly extending section (see Mills at col. 6, line 16) is capable or ever functions to pierce tissue. In fact, Mills specifically teaches otherwise. For the Mills clip to function as designed, the piston 205 is driven "leftwardly by means of the wire 206, thus driving the fourth section of the staple through the double layer of tissue so that its tip comes into contact with the anvil 260, and simultaneously deforming the remaining sections of the staple." Mills at col. 6, lines 26-28. Thus the Mills

device functions by driving the fourth section of the staple through the tissue rather than bending it through the tissue as the Examiner suggests. Indeed, because the Mills device requires piston 205 to drive the fourth section through the tissue and because there is only one piston, only one arm of the Mills staple can be a functionally piercing arm.

Respectfully, the examples recounted by the Examiner in item 14, paragraph 2, page 8 of the Office action, fail to appreciate the significance of this critical design feature of Mills.

In that paragraph, the Examiner gives the example of a cleric using his stapler. In the cleric example, both ends of the staple are designed to pierce the paper and, when the stapler is properly operated, both staple ends will pierce the paper. That the cleric did a poor job stapling and engaged only one of two functionally piercing arms does not change this fundamental design feature.

The Examiner also analogizes the invention of the present application with stepping on a sea urchin. The above argument applies equally -- each sea urchin needle functions and can be said to be designed to pierce, even though only one or two may do so when stepped on.

Finally, the Examiner analogizes the invention of the present application to a toothpick. In the case of the toothpick, each end of the toothpick is designed for the function of cleaning a space between teeth.

As the Mills patent discloses, only one end of the staple is intended and designed to pierce tissue. See Mills at FIGS. 5a-5c; col. 6, lines 14-19 and lines 25-28.

The Examiner's response appears to have made much of the use of the term "staple" and would be more appropriate if the staple disclosed in Mills were a U-shaped staple. But the Mills staple is not U-shaped. Rather it is trapezoidal with an open base. See Mills at FIGS. 5a to 5c. Unlike a typical staple in which both ends act to pierce, the Mills staple has an open base that acts as the single piercing tip.

It should be noted that the Mills staple depends entirely upon an anvil 260 and a piston 205 to drive its one piercing arm into a closed and secure position. Without the anvil and piston mechanism, the Mills staple will not close and cannot achieve its purpose of fastening the tissue as gathered in the clip-applying cavity of the device. In contrast, Applicants' present

invention requires neither anvil nor piston to close. Instead, the clip of the present invention is shut by the jaws of the grasper that is used to deliver the clip and plicate a fundus. See FIGS. 5 and 25. Thus, not only are the clips functionally and structurally different, they are applied in different manners and serve different purposes.

To the extent that the Examiner's rejection of claim 9 depends on the Examiner's position stated in item 2 of the Office action, i.e., "[u]sing logic, before the tissue can fit through the opening in the clipping device's cavity (202) it must already be in a folded condition", Applicants suggest that the Examiner is mistaken. Mills discloses that the tissue is gathered as it is drawn into the clip-applying cavity 202 by the suction channel 204 and not before. Mills at col. 6, lines 7-8. The Mills disclosure, therefore is entirely contrary to Examiner's position. Mills discloses no mechanism that would allow tissue to be folded and maintained in a folded state prior to insertion into the cavity 202.

With respect to the Examiner's rejection of claim 29, Applicants point out that nowhere in Mills is there any hint that the Mills' staple "applies force to the body tissue" that is "folded on itself" (i.e., invaginated) in the cavity 202 before a

piercing is bent through the tissue as set forth in claim 29.

The Examiner argues that the Mills clip will always apply at least the force of its own "weight (mass x gravity) on the fold". Such a conclusion, however, is nowhere supported from the disclosure of the surgical stapler in Mills. A careful examination of all of the description related to FIGS. 5a to 5c in col. 6, lines 1 to 41, in fact, teaches exactly the opposite.

Col. 6, lines 9 to 10, provide that, "[b]efore use, the cavity 202 is pre-loaded with a staple 209." Regardless of the staple 209 orientation, the staple 209 must be stationary after it is loaded in the cavity 202. If this was not the case and the staple 209 was loose, there would be a significant tendency for the staple 209 to not be in a position for proper stapling. The looseness of the staple 209, however, cannot be discussed without significant speculation because, in lines 20 to 22, Mills explicitly provides that "[i]n the condition shown in FIG. 5a suction has been applied to the channel 204 to suck into it a double layer of tissue 216." (Emphasis supplied by applicants.) Therefore, FIG. 5a only relates to the condition where significant suction is being imparted on the cavity 202 through the suction channel 204. Thus, there is absolutely no description or suggestion in Mills regarding the position of the staple 209 prior to the application of suction. Any argument

thereto, as proffered by the Examiner, is sheer conjecture. What is important to note is that while suction is being applied through the channel 204, that suction is **also being applied to the staple 209.** If the suction is sufficient to draw tissue 216 into the cavity 202, then it must be more than sufficient to draw the staple against the channel 204. With such a force acting against the staple 209 and, therefore, against gravity in whatever orientation the staple is disposed, there can be no force of the staple weight acting upon the tissue 216! It is respectfully submitted that a suction force sufficient to pull tissue 216 into the cavity 202 is many times greater than the weight of the staple 209. Accordingly, the Examiner's arguments regarding the insignificant weight of the staple as applying a force against the tissue prior to bending the piercing portion of the clip through the folded tissue cannot be accepted.

Applicants further note that there are more applications of Mills where the weight of the staple would apply absolutely no weight (force) to the tissue than there would be in applying such weight. First, one would have to entirely discount the requirement of suction through the channel 204 to get to this argument - a conclusion that can only be discussed in the hypothetical because Mills provides no disclosure or suggestion thereto. Second, the Mills staple would have to be applied to

tissue that only is positioned below the opening to the cavity 202, such as the orientation shown in FIGS. 5a to 5c. If, however, the tissue 216 was above stapler 200, then the weight of the staple 209 would be directed opposite the opening of the cavity 202 and never against the tissue 216. It is respectfully submitted that for a 360 degree orientation of the stapler 200 about an axis perpendicular to the cross-sectional plane in FIG. 5s, the staple 209, if it was rattling loose in the cavity 202, would only bear its weight on tissue for less than 60 degrees of orientation, but this would only occur if all suction was removed.

For all of these reasons, Mills does not disclose or suggest the features of claim 29.

The Examiner also rejects claims 31 to 33 as being fully anticipated by Mills. Claims 31 and 32 provides the step of "advancing a clip over body tissue folded on itself to form first and second portions of a fold disposed between the two arms and to apply a force to the folded body tissue, the folded tissue defining a longitudinal direction of the folded body tissue, the piercing portions of the two arms being initially oriented along the longitudinal direction." (Emphasis added by applicants.) Claim 33 similarly provides the steps of:

advancing a clip over two thicknesses of body tissue, the
clip having two arms each having a respective piercing
portion and a bridge coupling the two arms, such that the
body tissue is located between said two arms and such that
the clip applies force to the body tissue; and

subsequently bending the piercing portion of at least one
of the two arms through more than one of the thicknesses of
the body tissue.

As set forth above, each of the two arms of the independent
claims has a respective piercing portion, i.e., two piercing
portions, and the Mills device has only one. Each of the two
piercing portions of claims 31 and 32 of the instant application
are "initially oriented along the longitudinal direction." Not
only does the Mills device entirely fail to have or even suggest
two piercing portions, Mills only has one portion initially
oriented along the longitudinal direction - the **non-piercing**
fourth portion. Thus, Mills has no piercing portion "initially
oriented along the longitudinal direction" and cannot be said to
anticipate claims 31 or 32.

Furthermore, the Examiner's conflation of the limitation "initially oriented along the longitudinal direction" in claims 31 and 32 to mean merely "next to", "adjacent to" or "close to" or "by" (see item 16 on page 9 of the final Office action) ignores the function that the orientation plays in maintaining the shape of the plicated tissue and in imparting a force against the tissue prior to bending a portion through the tissue. The Examiner appears to have conceded as much, at least with respect to claim 32 by noting that "the piercing portion of Mills' clip cannot be considered to be oriented parallel to the longitudinal direction" but, nevertheless, does not withdraw his rejection of claim 32 on that basis. The Examiner's arguments ignore these features. Nowhere does Mills disclose a similar functional limitation and, thus, Mills cannot anticipate claims 31 and 32.

As is known, conventional staples (whether medical or clerical) pierce sheets of a material orthogonal to the plane of the sheets and bend the prongs that pierce through and already extend beyond the sheets in a direction along the sheets to hold the sheets together and to, thereby, provide a compressing/holding force in the piercing direction, specifically, between the head of the staple and the bent-over tips.

FIGS. 5a to 5c of Mills clearly show that the Mills staple 209 is very similar to a staple from, for example, a SWINGLINE® desk stapler. In particular, the single portion of the Mills staple that is to pierce the tissue enters the tissue perpendicular to the tissue fold while an anvil is placed on the opposite side of the tissue. Then, after completely piercing the tissue 216, the piercing portion is bent subsequently by the anvil 260 disposed on the other side of the piston 205. Simply put, the Mills stapler pierces straight portions orthogonally through the tissue and subsequently bends the straight portions with an external device (anvil 260) positioned on the opposite side of the tissue to cause the clenching force.

The piercing portion of the invention of claims 31 to 33, however, does not perform in this way. The clip of these claims is advanced over the body tissue in a longitudinal direction of the body tissue to be clipped. After advancing thereover, the piercing portion is caused to bend and, because of such bending, the tissue is pierced. Because Mills does not disclose the features of claims 31, 32, or 33 it cannot be said to anticipate these claims.

To even more clearly set forth the features of the present invention, claims 1, 27, 29, 31, 32, and 33 have been amended to have the two arms be two "substantially parallel" arms. Also, these claims have been amended to provide that the two arms "[remain] substantially parallel throughout the time the piercing portion of the at least one arm is bent."

Mills clearly does not have a clip with two substantially parallel arms each having a respective piercing portion and, more significantly, does not have two substantially parallel arms remaining substantially parallel "throughout the time the piercing portion . . . is bent." To the contrary, the trapezoidal arms begin at an angle with respect to one another and nowhere does Mills suggest or disclose that arms remain substantially parallel throughout the time the single piercing portion is bent. In fact, Mills teaches the opposite. As shown clearly in FIGS. 5a to 5c, as the single piercing portion is bent, all portions of the clip remain at an angle to one another and, therefore, none remain substantially parallel.

For the reasons discussed above, Mills cannot be said to anticipate claims 1, 27, 29, 31, 32, or 33. Dependent claims 5, 6, 9 to 11 and 30 are believed to be patentable as well because

they are all ultimately dependent upon allowable claims 1 and 29.

REJECTION OF CLAIMS UNDER TSURUTA ET AL.

In items 8 and 9 on pages 4 and 5 of the present Office Action, the Examiner also rejects claims 1, 3, 4, 12 and 26 as being anticipated pursuant to 35 U.S.C. § 102(b) by U.S. Patent 5,582,611 to Tsuruta et al. (hereinafter "Tsuruta"). Claim 1 calls for, *inter alia*, a medical method, including:

advancing a clip over body tissue, the clip having two substantially parallel arms each having a respective piercing portion such that the body tissue is located between the two arms; and

subsequently bending the piercing portion of at least one of the two arms through more than one half a thickness of the body tissue.

The Examiner contends on page 5 of the Office action that "[e]ach arm is bent through the entire thickness of the body tissue, such that the tips of the two arms contact each other [see progression from Figure 42B to Figure 42C]." (Italics original; underline added by applicants.) This conclusion is

incorrect because the "body tissue" that is being used by the Examiner is not the same "body tissue" that is defined in claim 1 and, therefore, cannot be analogized to the "body tissue" set forth in claim 1.

Applicants can be their own lexicographer. Thus, independent claim 1, itself, defines what the phrase "body tissue" means.

First, claim 1 provides that a clip is advanced over a feature referred to as "body tissue" so that the "body tissue" is located between the two arms. This means that whatever tissue that exists between the two arms is the "body tissue" of claim 1. Later in claim 1, one piercing portion is bent "through more than one-half a thickness of [this] body tissue." Looking at FIG. 25 of the instant application, for example, it can be clearly seen that a piercing portion is bent through more than one half of the thickness of the tissue that exists between the two arms. In stark contrast, the staple half of Tsuruta clearly is never bent through more than one half of the thickness of tissue between the two arms of staple 22. In fact, FIG. 39C explicitly shows that the *maximum* distance that an arm of the staple 22 is bent is no greater than half of the thickness of tissue between the two arms of the staple 22.

As shown clearly and explicitly in Tsuruta, and especially in FIGS. 39C, 42C, 43C, 49C, 53D, 55D, 59A, and 59B, each side of the staple 22a, 22b only pierces to a point where one side 22a of the staple 22 touches the other side 22b. Therefore, each piercing side only pierces *up to the half-way point* of the tissue therebetween, but not more. This limited extent is a required limitation of Tsuruta and nowhere does Tsuruta disclose or suggest having either side (22a, 22b) of the staple 22 pierce more than half of the way through the tissue between the two sides 22a, 22b. In fact, the Examiner admits on page 5 of the Office action that "*the tips of the two arms contact each other.*" (Emphasis original.) Thus, each arm *prevents* the other arm from piercing past the half-way point. It is noted that FIGS. 57C, 60B, 60C, 62B, and 62C show embodiments where the tips of the staple are not even touching - thus, they cannot even be considered as entirely piercing through even one of the two layers of tissue present between the tips.

The Examiner states that Tsuruta discloses, in FIGS. 42 and 43, that the Tsuruta "clip (22) has two arms and bridge coupling the arms, as shown in Figure 61" and also states that "the clip applies force to the body tissue." However, the Examiner incorrectly contends that "[e]ach arm is bent through the entire

thickness of the body tissue such that the tips of the two arms contact each other." (Emphasis original.)

The Tsuruta rejection is entirely silent on the Tsuruta clip 22 "advancing over" any body tissue. This is because the Tsuruta clip does not disclose or suggest advancing the clip 22 over body tissue. Tsuruta does not "advance over" the tissue because, as shown clearly in FIGS. 39A to 39C, 42A to 42C, 43A to 43C, 49A to 49C, 53A to 53D, 55A to 55D, 59A to 59B, 60A to 60C, and 62A to 62C, the Tsuruta clip 22 only pierces into the tissue. In contrast, claims 1 and 33 clearly provide that a clip is advanced over the body tissue between the two arms. Because Tsuruta does not disclose or suggest such a feature, it cannot be said to anticipate claim 1.

In fact, Tsuruta discloses a device that is directed not toward clipping plicated tissue but, rather, for the control of bleeding in tissue that has been severed or cut during surgical procedures. See Col. 2, lines 24 to 33. Indeed in the embodiments referenced by Examiner, Tsuruta employs either a vacuum tube or scoop for drawing one section of incised tissue to another so that a surgeon may then apply a staple to close the wound. See FIGS. 42A to 42C and 43A to 43C; col.18, lines 4-10; col. 18, lines 17-25. Like Mills, the Tsuruta staple

relies on a piston and anvil to bend the staple into place and thereby secure the incised tissues to one and other. See FIGS. 35A to 35C. In Tsuruta, the anvil is placed directly against the bridge of the staple and between the staple's two retracted arms. The piston applies pressure directly to the retracted arms of the staple which then pierces the tissue and closes the incision. See FIGS. 35A to 35C; 42A to 42C; and 43A to 43C. In the present invention, tissue is gathered into the clip, which is then closed. When tissue is pierced in the present invention, it is pierced not for the purpose of controlling bleeding and facilitating the healing of a surgical incision as in Tsuruta, see col. 18, lines 17 to 22, but, rather, for the purposes of securing the reshaped fundus for the treatment of GERD.

Indeed, the function of the Tsuruta staple, i.e., to endoscopically join cut tissues, explains the difference in appearance between the staple provided for in Tsuruta and the clip of the present invention. In the present invention, the clip, elongated when compared to Tsuruta, is used to secure plicated tissue that has been gathered into the junction between the clip arms. When the clip is secured, the plicated tissue retains its folded shape. In contrast, Tsuruta discloses a staple that binds cut tissue that has been drawn together in

order to control bleeding and promote healing. Tsuruta discloses a device and limitations suitable for that purpose. Tsuruta could not function for the purpose of the present invention, however, and would be incapable of securing folded portions of the fundus, as the present clip does, in the treatment of GERD.

The Examiner has also rejected claim 12 by arguing that Tsuruta, at FIG. 42A, discloses that the Tsuruta staple binds two separate pieces of tissue. However, Tsuruta at col. 17, line 66, to col. 18, line 10, discloses that the staple is used to close "wounds", i.e., to close severed tissue. See Tsuruta at col. 18, line 8. Thus, the staple does not bind two separate pieces of tissue, but rather one piece that has been cut.

For the reasons discussed above, Tsuruta does not anticipate claim 1. Dependent claims 3, 4, 12 and 26 are believed to be patentable as well because they are all ultimately dependent upon claim 1.

REJECTION OF CLAIMS UNDER BOLANOS ET AL.

On page 5 of the above-identified Office action, claims 7 and 8 have been rejected as being obvious over Mills in view of U.S.

Patent No. 5,571,116 to Bolanos et al. (hereinafter "Bolanos")
under 35 U.S.C. § 103.

Insofar as claim 1 is believed to be allowable, and due to the fact that claims 7 and 8 ultimately depend upon claim 1, the rejection of these claims is now believed to be moot.

Just like Mills, Bolanos' staple 30 is similar to a conventional desktop stapler. Specifically, the portion of the staple 30 that is to pierce the tissue enters the tissue perpendicular to the tissue fold while an anvil 26 is placed on the opposite side of the tissue (see anvil recesses 33 in FIG. 6A, 6B, and 8).

Then, after completely piercing the tissue, the pierced and orthogonally extending portion is bent by the anvil 26 disposed on the other side of the staple ejector 28. See Bolanos at FIGS. 6B and 8. Nowhere does Bolanos disclose or suggest "advancing a clip over body tissue" as set forth in claim 1. Thus, Bolanos cannot suggest claim 1 of the instant application, let alone claims 7 and 8.

With all due respect to the Examiner's statement in item 10 of the final Office action, Mills at col. 6, lines 30 to 38, actually describes FIG. 5c. This cited text does not disclose manipulating two adjacent folds of tissue but, rather, a single

one that is stapled as described above. While there is a disclosure that multiple staples may be used, there is no indication, unlike in claim 7 of the present invention, that multiple folds of tissue may be stapled by the device. Indeed simple examination of Mills produces a sole conclusion that only one fold of tissue may be drawn into the cavity 202 at any one time because there is only a single cavity present. Thus, not only does Mills fail to disclose multiple folds of tissue being stapled together by one or more clips, the device discloses no mechanism to allow for multiple folds to be drawn together and clipped.

Bolanos is used to complete the Section 103 combination rejection for using a clip on a fundus. However, Bolanos discloses a method for securing plicated folds of tissue that is fundamentally different than that disclosed by the present invention. As described above, the staple disclosed by Bolanos completely pierces the plicated tissue as the orthogonally extending arm of the staple perforates the tissue and is, then, bent by the anvil 26 disposed on the other side of the staple ejector. Nowhere does Bolanos suggest advancing the clip over tissue. Examiner's response in item 18 on page 9 shows a fundamental misunderstanding of this point when the Examiner equates the terms "over" with "through" by suggesting that the

"clip is advanced over/through tissue" in Bolanos. The present device does not maintain the plicated folds of the fundus by stapling through them as does Bolanos. See, i.e., FIGS. 6A and 6B, and col. 5, line 41, to col. 6, line 6. Rather, the present device functions by advancing the clip over the plicated tissue, i.e., with the tissue positioned between the advancing arms of the clip, and then securing the folded tissue within the arms.

Nor can the Examiner's position be well taken when it is surmised that the Bolanos staple performs advancement over tissue by virtue of the fact that the staple is driven through the tissue. See Item 18 on page 9 of the final Office action. As set forth in claim 7, the method includes "advancing a clip over body tissue," i.e., with tissue between its arms so that the plicated tissue will remain in place. Thus, the "advancing . . . over body tissue" feature of the claim is an important dimension to the functioning of the present invention. The Examiner has cited to no similar function in the Bolanos staple 30. Because the Bolanos staple secures the plicated tissue by perforating it, there is no similar functional dimension in Bolanos and the Examiner errs in extending the definition of the term "advancing over" as he has in the context of the Bolanos staple.

It is well settled that almost all claimed inventions are but novel combinations of old features. The courts have held in this context, however, that when "it is necessary to select elements of various teachings in order to form the claimed invention, we ascertain whether there is any suggestion or motivation **in the prior art** to make the selection made by the applicant". Interconnect Planning Corp. v. Feil, 227 USPQ 543, 551 (Fed. Cir. 1985) (emphasis added). "Obviousness can not be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combination". In re Bond, 15 USPQ2d 1566, 1568 (Fed. Cir. 1990). "Under Section 103 teachings of references can be combined **only** if there is some suggestion or incentive to do so." ACS Hospital Systems, Inc. v. Montefiore Hospital et al., 221 USPQ 929, 933, 732 F.2d 1572 (Fed. Cir. 1984) (emphasis original). "Although a reference need not expressly teach that the disclosure contained therein should be combined with another, the showing of combinability, in whatever form, must nevertheless be '**clear and particular.**'" Winner Int'l Royalty Corp. v. Wang, 53 USPQ2d 1580, 1587, 202 F.3d 1340 (Fed. Cir. 2000) (emphasis added; citations omitted); Brown & Williamson Tobacco Corp. v. Philip Morris, Inc., 56 USPQ2d 1456, 1459 (Fed. Cir. Oct. 17, 2000). Applicants believe that there is no "clear and particular" teaching or suggestion in Mills to

incorporate the features of Bolanos, and there is no teaching or suggestion in Bolanos to incorporate the features of Mills.

In establishing a *prima facie* case of obviousness, it is incumbent upon the Examiner to provide a reason why one of ordinary skill in the art would have been led to modify a prior art reference or to combine reference teachings to arrive at the claimed invention. Ex parte Clapp, 227 USPQ 972, 973 (Bd. Pat. App. & Int. 1985). To this end, the requisite motivation must stem from some teaching, suggestion, or inference in the prior art as a whole or from the knowledge generally available to one of ordinary skill in the art and not from the applicants' disclosure. See, for example, Uniroyal, Inc. v. Rudkin-Wiley Corp., 837 F.2d 1044, 1052, 5 USPQ2d 1434, 1439 (Fed. Cir. 1988), cert. den., 488 U.S. 825 (1988). The Examiner has not provided the requisite reason why one of ordinary skill in the art would have been led to modify Mills or Bolanos or to combine Mills' and Bolanos' teachings to arrive at the claimed invention. Further, the Examiner has not shown the requisite motivation from some teaching, suggestion, or inference in Mills or Bolanos or from knowledge available to those skilled in the art.

Applicants respectfully believe that any teaching, suggestion, or incentive possibly derived from the prior art is only present with hindsight judgment in view of the instant application. "It is impermissible, however, simply to engage in a hindsight reconstruction of the claimed invention, using the applicant's structure as a template and selecting elements from references to fill the gaps. . . . The references **themselves** must provide some teaching whereby the applicant's combination would have been obvious." In re Gorman, 18 USPQ2d 1885, 1888 (Fed. Cir. 1991) (emphasis added). Here, no such teaching is present in the cited references.

It is accordingly believed to be clear that none of the references, whether taken alone or in any combination, either show or suggest the features of claims 7 or 8. The claims are therefore believed to be allowable over the prior art.

ADDITION OF CLAIMS 34 AND 35

The Examiner has indicated that claim 28 would be allowable if rewritten in independent form.

Claims 34 and 35 have been added. Claim 34 combines the features of claims 27 and 28. Thus, claim 34 is allowable.

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Claim 35 is dependent upon claim 34 and is, therefore, allowable as well.

In view of the foregoing, reconsideration and allowance of claims 1 to 35 are solicited.

In the event the Examiner should still find any of the claims to be unpatentable, counsel would appreciate receiving a telephone call so that, if possible, patentable language can be worked out.

Respectfully submitted,

For Applicants

GLM:tk

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